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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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BARNES & THORNBURG
P.O. BOX 2786
CHICAGO, IL 60690-2786

EXAMINER

MARTINELL, JAMES

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| ART UNIT | PAPER NUMBER |
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1631

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/897,798

Applicant(s)

WESTBROOK ET AL.

Examiner

James Martinell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/3/04 & 6/5/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-22 is/are pending in the application.
- 4a) Of the above claim(s) 4-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Claims 4-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 9, 2003.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, incomplete, inaccurate, and misdescriptive.

- (a) The recitation of "wherein a majority of the DNA molecules are expressed in hematopoietic tissue of a primate" (claim 12) is vague, indefinite, and incomplete because the application does not define a set of molecules for such a purpose as is mentioned in the claim. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed September 3, 2003, page 3, item (a)). A broad recitation of an intended purpose does not define or adequately describe the claimed collection of molecules. The claim merely describes a desired result and not the structures of the molecules attached to the microchip.
- (b) Claims 14 and 15 are incomplete in referring to Appendix A. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed September 3, 2003, page 3, item (b)). Applicants assert that there is no prohibition in MPMP 608.01(p) for a claim to refer to an appendix (response filed February 3, 2004, page 10). This is correct. However, it is noted that the rejection did not state that MPEP 608.01(p) prohibits a claim from referring to an appendix. It is reiterated that there is no provision for a claim to refer to an appendix. What MPEP 608.01(p) was and still is relied upon for is the improper incorporation by reference to essential subject matter. The references given in appendix A are to essential subject matter and are thus improper incorporations by reference

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(MPEP 608.01(p)). Applicants' assertion (response filed February 3, 2004, page 10) that the GenBank® accession numbers are known is most unconvincing because the incorporation of essential subject matter may be made by reference only to allowed U.S. Patent applications or issued U.S. Patents. In addition, applicants have not established for the record just what was available in GenBank® as of the effective filing date of the instant claims.

- (c) The recitation of "analysis is to determine . . . engraft for transplantation" (claim 16) is vague and indefinite because a broad recitation of an intended purpose does not define or adequately describe the claimed collection of molecules. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed September 3, 2003, page 3, item (e)). It is noted that applicants have not argued this ground of rejection.
- (d) Claims 16-22 are vague and indefinite because a broad recitation of an intended purpose does not define or adequately describe the claimed collection of molecules. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed September 3, 2003, page 3, item (f)). It is noted that applicants have not argued this ground of rejection.
- (e) The recitation of "wherein the expression analysis is to determined if a stem cell graft needs to be expanded *ex vivo*" is vague and indefinite because the passage does not make grammatical sense.
- (f) The recitation of "wherein the expression analysis is to determined if a stem cell graft needs to be expanded *ex vivo*" is vague and indefinite because a broad recitation of an intended purpose does not define or adequately describe the claimed collection of molecules. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed September 3, 2003, page 3, item (g)). It is noted that applicants have not argued this ground of rejection.

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- (g) The recitation of "analysis is to determine . . . pharmacological treatment" (claim 18) is vague and indefinite because a broad recitation of an intended purpose does not define or adequately describe the claimed collection of molecules. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed September 3, 2003, page 4, item (i)). It is noted that applicants have not argued this ground of rejection.
- (h) The recitation of "expression analysis is to identify genes relevant to hematopoiesis" (claim 19) is vague, indefinite, and incomplete because a broad recitation of an intended purpose does not define or adequately describe the claimed collection of molecules. Applicants' argument (response filed February 3, 2004, paragraph bridging pages 9-10) is not convincing. First, Kuby, *Immunology*, 3rd Ed., pp. 47-49 is not of record and is therefore given no weight. Second, the reliance on genes listed in Appendix A is not convincing because the information about those genes is contained in material that is not actually in the record and is an improper incorporation by reference (see item (a) hereinabove). Finally, the term "relevant to" is vague and indefinite because the instant application makes no distinction between genes relevant to hematopoiesis and gene irrelevant to hematopoiesis.
- (i) The recitation of "wherein the expression analysis is to determine if gene therapy altered expression levels of the cDNA molecules in the microchip" (claim 20) is vague, indefinite, inaccurate, and misdescriptive. Expression levels of the microchip are not changed. The claim is vague and indefinite because a broad recitation of an intended purpose does not define or adequately describe the claimed collections of molecules.
- (j) The recitation of "wherein the expression analysis is to determine if gene therapy altered expression levels of the cDNA molecules in the microchip" (claim 20) is

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vague and indefinite because the instant application does not define what is meant by "gene therapy" and there is no art-recognized meaning for the term. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed September 3, 2003, page 5, item (s)). Applicants' argument (response filed February 3, 2004, page 10) is not convincing. First, Griffiths et al is given no weight because it is not in the record. Second, the "definition" referred to on page 11, lines 5-6 of the instant application is not a definition at all, but mere usage of the term.

- (k) The recitation of "treatment with growth factors" (claim 21) is vague and indefinite because the instant application does not define the group "growth factors." It is noted that applicants have not argued this rejection.
- (l) The recitation of "the data set comprising . . . analysis of hematopoietic tissue" (claim 22) is vague, indefinite, and incomplete because a broad recitation of an intended purpose does not define or adequately describe the claimed collections of molecules. It is noted that applicants have not argued this rejection.

Claims 12-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of "hematopoietic tissue of a primate" in claim 12 as amended February 3, 2004 is new matter.

Claims 12-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed September 3, 2003, paragraph bridging pages 5-6). Applicants did not specifically address this ground of rejection.

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Claims 12-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed September 3, 2003, first full paragraph on page 6). Applicants' arguments (response filed February 3, 2004, section V on pages 10-11) are not convincing because applicants have not established just what was in GenBank® as of the effective filing date of the claims. In addition, applicants have not addressed the issue of the claims being inadequately described in writing, thus making it impossible for one of skill in the art to practice the claimed invention.

Claims 12-22 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed September 3, 2003, page 6). Applicants' arguments (response filed February 3, 2004, section III, pages 7-8) are not convincing because applicants do not point to a specific utility for any specific microarray embraced by the claims.

Claims 12-22 are rejected under 35 U.S.C. 102(a) or (b) as being clearly anticipated by research Genetics, Huntsville, AL. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed September 3, 2003, paragraph bridging pages 6-7). Applicants' arguments (response filed February 3, 2004, section VI on page 11) are not convincing because applicants have shown no difference between the microchips of the reference and those of the claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

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action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

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PLEASE NOTE THE NEW FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is
(703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


James Martinell, Ph.D.
Primary Examiner
Art Unit 1631

8/30/04